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QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR PURIFIED WATER

S.No.	Description	Risk Identification			Risk Evaluation			Risk Control			
		Failure Mode	Effect	Cause	Impact: C, M, m,b	Detectability: H, M, L	Initial Risk	Risk Mitigation	Final Risk	Risk Verification	Risk Acceptance
1	Incoming Water	Not applicable since the incoming water is controlled by city regulation laws	No Sampling	Unknown since no sampling	C	H	H	From the mid-point to the final stages of purification process there are quality indicators in place such as total organic carbon (TOC,) conductivity, and ultraviolet (UV) data measurements.	M	Verified during PQ and Routine quality control (QC) sampling phase (post-PQ Phase, the moment the system is accepted or handed over to operations within the operational phase). Refer to rationale Table II for additional explanation.	L
2	Filtered incoming Water – Cartridge Filter Product Water	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	M	H	L	From the mid-point to the final stages of purification process there are quality indicators in place such as TOC, conductivity, and UV data measurements.	L	Verified during routine QC sampling phase (post-PQ phase, the moment the system is accepted or handed over to operations within the operational phase). Refer to rationale Table II for additional explanation.	L
3	Water Softening Unit S-1 Product Water	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	M	H	M	From the mid-point to the final stages of purification process there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during PQ and Routine QC sampling phase (post PQ phase, the moment the system is accepted or handed over to operations within the operational phase). Refer to rationale Table II for additional explanation.	L
4	Water Softening Unit S-2 Product Water	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	M	M	M	From the mid-point to the final stages of purification process there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during PQ and routine QC sampling phase (post PQ phase, the moment the system is accepted or handed over to operations within the operational phase). Refer to rationale Table II for additional explanation.	L
5	Activated Carbon Cartridge Filtration System Product	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	M	M	M	From the mid-point to the final stages of purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during PQ and routine QC sampling phase (post-PQ Phase, the moment the system is accepted or handed over to operations within the operational phase]. Refer to rationale in Table II for additional explanation.	L
6	Post-Pre-treatment Cartridge Filter Product	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	M	M	L	From the mid-point to the final stages of purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	L	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
7	RO Product Water	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	M	M	L	From the mid-point to the final stages of purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	L	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L

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8	RO Product Water	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	M	M	L	From the mid-point to the final stages of purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	L	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
9	RO Product Water	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	M	M	L	From the mid-point to the final stages of purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	L	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
10	RO Product Water	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	M	M	L	From the mid-point to the final stages of purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	L	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
11	RO Product Water	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	M	M	L	From the mid-point to the final stages of purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	L	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
12	RO Product Water	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	M	M	L	From the mid-point to the final stages of purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	L	Verified during Routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
13	RO Product Water	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	C	H	M	From the mid-point to the final stages of purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.		Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
14	USP Purified Water Distribution Loop Return	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	C	H	H	From the mid-point to the final stages of purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
15	USP Purified Water Storage Tank Water (Pump Discharge)	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	C	H	H	From the mid-point to the final stages of purification process, there are quality indicators in place such as TOC, conductivity, and UV data	M	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L

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S.No.	Description	Risk Identification			Risk Evaluation			Risk Control			
		Failure Mode	Effect	Cause	Impact: C, M, m,b	Detectability: H, M, L	Initial Risk	Risk Mitigation	Final Risk	Risk Verification	Risk Acceptance
								measurements.			
16	Loop Rechargeable Mixed Bed Canister System Product Water	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	C	H	H	From the mid-point to the final stages of purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
17	Loop Rechargeable Mixed Bed Canister System Product Water	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	C	H	H	From the mid-point to the final stages of purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
18	Loop Inline Ultraviolet Sanitization Unit Product Water	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	C	H	H	From the mid-point to the final stages of purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during PQ and routine QC sampling phase. Refer to rationale Table II for additional explanation.	L
19	0.1 Micron Final Membrane Filter 1st, Product Water	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	C	H	H	From the mid-point to the final stages of purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during PQ and routine QC sampling phase. Refer to rationale Table II for additional explanation	L
20	0.1 Micron Final Membrane Filter, 2nd, Product Water	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	C	H	H	From the mid-point to the final stages of purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during PQ and routine QC sampling phase. Refer to rationale Table II for additional explanation	L
21	USP Purified Water Distribution Loop Feed Water [Points of Uses]	Equipment not reducing impurities per design	No Sampling	Unknown since no sampling	C	H	H	From the mid-point to the final stages of purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during PQ and routine QC sampling phase. Refer to rationale Table II for additional explanation	L

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Sampling Plan Summary for the Generic RO/DI Skid.

Tag #	Description	Test	Rationale
SP-01	Incoming Water	**Frequency: Twice During Three Weeks**: pH, Total Chlorine Concentration, Free Chlorine Concentration, Total Iron, Manganese, TOC, Turbidity, Conductivity at 25°C, Total Alkalinity as Calcium Carbonate, Sulfate, Barium, Total Hardness as Calcium Carbonate, Sodium, Chloride, Total Suspended Solids, Silica. Testing for Total Viable Bacteria count	Since the output of the incoming water will be undergoing further purification steps, it is suggested to test twice during a three-week period to determine the quality of the water at the beginning prior to any pre-treatment purification/processing steps. **Risk Control:** The sampling activities and frequencies shall be done per test instruction within the PQ phase in addition to the routine sampling (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring over and above]
SP-02	Filtered Raw Feed Water – Cartridge Filter Product Water	Not Applicable	No need to perform this test **(the water generation system is new)** since it has been tested for water quality at sample site SP-01, and this would result in very little to no added value since other sampling points at further purification stages will capture the quality output. **Risk Control:** The sampling activities and frequencies shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SP-03	Water Softening Unit S-1 Product Water	**Frequency: Two Days/Week for Three Weeks:** Total Hardness as Calcium Carbonate	Only suggested to test for total hardness as calcium carbonate during this purification-processing step. It is important to ensure consistency in sample output/data at the beginning and end of the week during a three-week period. Performing this test daily would not necessarily support any added value since other sampling points at further purification stages will capture the quality output. **Risk Control:** The sampling activities and frequencies shall be done per test instruction within the PQ phase in addition to the routine sampling (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring over and above).
SP-04	Water Softening Unit S-2 Product Water	**Frequency: Two Days/Week for Three Weeks**: Total Hardness as Calcium Carbonate	Only suggested to test for total hardness as calcium carbonate during this purification processing step. It is important to ensure consistency in sample output/data at the beginning and end of the week during a three-week period. Performing this test daily would not necessarily support any added value since other sampling points at further purification stages will capture the quality output. **Risk Control:** The sampling activities and frequencies shall be done per test instruction within the PQ phase in addition to the routine sampling (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring over and above).
SP-05	Activated Carbon Cartridge	**Frequency: Two Days/Week for Three Weeks:** Total	To ensure that at the activated carbon cartridge filtration system product water component purification stage, the total chlorine concentration remains in control within acceptable range based on its previous purification

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Tag #	Description	Test	Rationale
	Filtration System Product Water	Chlorine Concentration	processing steps coupled with its design function. **Risk Control:** The sampling activities and frequencies shall be done per test instruction within the PQ phase in addition to the routine sampling (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring over and above).
SP-06	Post-Pretreatment Cartridge Filter Product	Not Applicable	No need to perform this test **(the water generation system is new)** since it has been tested for water quality at sample site SP-13, and this would result in very little to no added value since other sampling-points at further purification stages will capture the quality output. **Risk Control:** The sampling activities and frequencies shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SP-07	RO Product Water	Not Applicable	No need to perform this test **(the water generation system is new)** since it has been tested for water quality at sample site SP-13, and this would result in very little to no added value since other sampling points at further purification stages will capture the quality output. **Risk Control:** The sampling activities and frequencies shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SP-08	RO Product Water	Not Applicable	No need to perform this test **(the water generation system is new)** since it has been tested for water quality at sample site SP-13, and this would result in very little to no added value since other sampling points at further purification stages will capture the quality output. **Risk Control:** The sampling activities, and frequencies shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SP-09	RO Product Water	Not Applicable	No need to perform this test **(the water generation system is new)** since it has been tested for water quality at sample site SP-13, and this would result in very little to no added value since other sampling points at further purification stages will capture the quality output. **Risk Control:** The sampling activities and frequencies shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SP-10	RO Product Water	Not Applicable	No need to perform this test **(the water generation system is new)** since it has been tested for water quality at

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Tag #	Description	Test	Rationale
			sample site SP-13, and this would result in very little to no added value since other sampling points at further purification stages will capture the quality output. **Risk Control:** The sampling activities, and frequencies shall be done in routine sampling phase (e.g., sample Randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SP-11	RO Product Water	Not Applicable	No need to perform this test **(the water generation system is new)** since it has been tested for water quality at sample site SP-13, and this would result in very little to no added value since other sampling points at further purification stages will capture the quality output. **Risk Control:** The sampling activities, and frequencies shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SP-12	RO Product Water	Not Applicable	No need to perform this test **(the water generation system is new)** since it has been tested for water quality at sample site SP-13, and this would result in very little to no added value since other sampling points at further purification stages will capture the quality output. **Risk Control:** The sampling activities and frequencies shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SP-13	RO Product Water	**Frequency: Two Days/Week for Three Weeks:** Conductivity at 25°C, pH, TOC	Only TOC and conductivity tests are needed at this point since there would be no added value to test for other parameters such as total Alkalinity as Calcium Carbonate and Total Viable Bacteria due to the fact that they have been previously removed during the purification processing steps and tested. **Risk Control:** The sampling activities and frequencies shall be done per test instruction within the PQ phase in addition to the routine sampling (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring over and above).
SP-14	USP Purified Water Distribution Loop Return	**Frequency: Two Days/Week for Three Weeks:** TOC per *USP* “Physical Tests” <643>, Conductivity per USP “Physical Tests”<645>, Total Viable Bacteria	To ensure that critical testing components such as TOC, conductivity, and total viable bacteria remain within acceptable limits. **Risk Control:** The sampling activities and frequencies shall be done per test instruction within the PQ phase in addition to the routine sampling (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring over and above).
SP-15	USP Purified Water Storage Tank Water (Pump	**Frequency: Two Days/Week for Three Weeks:** Conductivity at 25°C, TOC, Total Viable Bacteria	To ensure that critical testing components such as TOC, conductivity, and total viable bacteria remain within acceptable limits

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Tag #	Description	Test	Rationale
	Discharge)		**Risk Control:** The sampling activities and frequencies shall be done per test instruction within the PQ phase in addition to the routine sampling (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring over and above).
SP-16	Loop Rechargeable Mixed Bed Canister System Product Water	Not Applicable	No added value to test **(the water generation system is new)** at this point since it will be tested at the output of UV unit sample site (SP-18) for a better representative sample. **Risk Control:** The sampling activities and frequencies shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SP-17	Loop Rechargeable Mixed Bed Canister System Product Water	Not Applicable	No added value to test **(the water generation system is new)** at this point since it will be tested at the output of UV unit sample site (SP-18) for a better representative sample. **Risk Control:** The sampling activities and frequencies shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SP-18	Loop Inline Ultraviolet Sanitization Unit Product Water	**Frequency: Two days/Week for Three Weeks:** Total Viable Bacteria	To ensure that at the loop inline ultraviolet sanitization unit product water component purification stage, the total viable bacteria remains in control within acceptable range based on its previous purification processing steps coupled with its design function. **Risk Control:** The sampling activities and frequencies shall be done per test instruction within the PQ phase in addition to the routine sampling (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring over and above).
SP-19	0.1 Micron Final Membrane Filter, FF-1, Product Water	Not Applicable	No added value to test at this point **(the water generation system is new)** since it will be tested at sample site (SP-21) prior to point-of-uses. **Risk Control:** The sampling activities and frequencies shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SP-20	0.1 Micron Final Membrane Filter, FF-2, Product Water	Not Applicable	No added value to test **(the water generation system is new)** at this point since it will be tested at sample site (SP-21) prior to point-of-uses. **Risk Control:** The sampling activities and frequencies shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SP-21	USP Purified	**Frequency: Two Days/Week for Three Weeks:**	To ensure that the USP purified water distribution loop feed water component purification stage is maintaining

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Tag #	Description	Test	Rationale
	Water Distribution Loop Feed Water [Point of Uses]	Total Organic Carbon per *USP*" Physical Tests" Section <643>,Conductivity per *USP* "Physical Tests" Section <645>, Total Viable Bacteria	the TOC and conductivity within acceptable range based on its previous purification processing steps coupled with its design function. **Risk Control:** The sampling activities and frequencies shall be done per test instruction within the PQ phase in addition to the routine sampling (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring over and above)